General

Guideline Title

Diagnosis and treatment of osteoporosis.

Bibliographic Source(s)

Allen S, Forney-Gorman A, Homan M, Kearns A, Kramlinger A, Sauer M. Diagnosis and treatment of osteoporosis. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2017 Jul. 61 p.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Florence R, Allen S, Benedict L, Compo R, Jensen A, Kalogeropoulou D, Kearns A, Larson S, Mallen E, O'Day K, Peltier A, Webb B. Diagnosis and treatment of osteoporosis. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2013 Jul. 87 p. [210 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition

YES	Multidisciplinary Group
UNKNOWN	Methodologist Involvement
■■□□□	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
■■■■□	Search Strategy
■■■■□	Study Selection
■■■■■	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
■■■■□	Grading the Quality or Strength of Evidence
■■■■■	Benefits and Harms of Recommendations
■■■■■	Evidence Summary Supporting Recommendations
■■■■□	Rating the Strength of Recommendations
■■■■□	**Specific and Unambiguous Articulation of Recommendations**
■■□□□	**External Review**
■■■■□	**Updating**

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): The recommendations for diagnosis and treatment of osteoporosis are presented in the form of a table with a list of evidence-based recommendations and an algorithm, accompanied by detailed annotations. The algorithms are provided in the original guideline document at the ICSI Web site for Diagnosis and Treatment of Osteoporosis (see the "Guideline Availability" field). In addition, ungraded Work Group Consensus Recommendations on bone mineral density (BMD) screening, shared decision making, and further risk assessment can be found in the Recommendation Table in the original guideline document.

Class of evidence (Low Quality, Moderate Quality, and High Quality) and strength of recommendation (Weak or Strong) definitions are provided at the end of the "Major Recommendations" field.

Counseling on Lifestyle Modification

Recommendation: Primary prevention and treatment for low bone density should include counseling on lifestyle modification regarding nutrition, physical activity, smoking and alcohol. (Quality of Evidence: Low; Strength of Recommendation: Strong)

Benefit: Lifestyle modifications can improve bone mineral density. They also have positive implications for many other health conditions.
Harm: There is no harm in counseling patients on self-management of lifestyle factors. One consideration from a resource perspective is time needed for clinicians to have these conversations. However, because nutrition, physical activity, smoking and alcohol affect health in many ways, this time is well spent as a prevention tool.
Benefit-Harms Assessment: The benefit of discussing lifestyle factors with patients far exceed any negligible harms related to time and resources.
Relevant Resources: Hannan et al., 2000; Huopio et al., 2000; Høidrup et al., 1999; Ulrich et al., 1999

Bone Mineral Density (BMD) Assessment

Recommendation: When available, central dual-energy x-ray absorptiometry (DXA) is the preferred method for assessing bone mineral density. (Quality of Evidence: Low; Strength of Recommendation: Strong)

Benefit: DXA is widely available, non-invasive, and has low radiation exposure. Most of the trials on pharmacologic therapy utilized DXA as the diagnostic tool for osteoporosis.
Harm: There is radiation exposure for DXA, which, although small, is still present.
Benefit-Harm Assessment: The benefits of DXA as a diagnostic tool outweigh the small risk of radiation that is involved.
Relevant Resource: Hailey et al., 1998

Pharmacologic Treatment

Recommendation: Bisphosphonates should be considered (unless contraindicated) for reduction of fracture risk (both vertebral and non-vertebral) in:

Postmenopausal women with osteoporosis
Men with osteoporosis

(Quality of Evidence: Postmenopausal women with osteoporosis [High]; Men with osteoporosis [Moderate]; Strength of Recommendation: Strong)

Benefit: Bisphosphonates have been shown to improve bone mineral density and reduce the incidence of fracture.
Harm: As with any medication, bisphosphonates may be associated with side effects. While rare, osteonecrosis of the jaw is a serious adverse effect of bisphosphonates, as are atypical femur fractures.
Benefit-Harm Assessment: For most patients with osteoporosis, the benefits of the medication outweigh the risks. However, the benefit-harm assessment should be done for each individual patient to evaluate whether this medication is appropriate.
Relevant Resources:
Postmenopausal women with osteoporosis: Eriksen, Diez-Perez, & Boonen, 2014; Miller et al., 2012; Eisman et al., 2008; Black et al., 2007; Chestnut et al., 2005; Chestnut et al., 2004; McClung et al., 2001; Black et al., 2000; Fogelman et al., 2000; Harris et al., 1999
Men with osteoporosis: Chen et al., 2015

Definitions

Category	Quality Definitions	Strong Recommendation	Weak Recommendation
High Quality Evidence	Further research is very unlikely to change confidence in the estimate of effect.	The work group is confident that the desirable effects of adhering to this recommendation	The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient

Category	Quality Definitions	Strong Recommendation	Weak Recommendation
		outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients.	values or preferences.
Moderate Quality Evidence	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.	The work group is confident that the benefits outweigh the risks, but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients.	The work group recognizes that there is a balance between harms and benefit, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances.
Low Quality Evidence	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change. The estimate or any estimate of effect is very uncertain.	The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.	The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms.

Clinical Algorithm(s)

A detailed and annotated clinical algorithm titled "Diagnosis and Treatment of Osteoporosis" is provided in the original guideline document (see the "Guideline Availability" field).

Scope

Disease/Condition(s)

Osteoporosis and osteoporotic fractures

Guideline Category

Diagnosis

Evaluation

Management

Prevention

Risk Assessment

Screening

Treatment

Clinical Specialty

Endocrinology

Family Practice

Geriatrics

Internal Medicine

Obstetrics and Gynecology

Preventive Medicine

Rheumatology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To address the prevention, diagnosis and management of bone loss in adults age 18 and older, including lifestyle modification, evaluation and drug treatment
- To increase the percentage of adults appropriately screened for osteoporosis

Target Population

Adults age 18 and older

Note: This guideline does not address the pediatric population.

Interventions and Practices Considered

1. Risk assessment
2. Shared decision making
3. Counseling on lifestyle modification regarding nutrition, physical activity, smoking, and alcohol
4. Bone mineral density assessment using central dual-energy x-ray absorptiometry (DXA)
5. Bisphosphonates

Major Outcomes Considered

- Fracture risk (absolute risk, relative risk, and incidence)
- Predictive value of bone mineral density measurements
- Effects of prevention/treatment interventions on bone density, bone loss, bone health, and fracture

risk
- Adverse effects of medications

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search

A consistent and defined literature search process is used in the development and revision of Institute for Clinical Systems Improvement (ICSI) guidelines. A formal literature search was conducted in PubMed. It included systematic reviews, meta-analyses, randomized controlled trials and observational studies, and was limited to adults over 18 years of age. The search was from January 1, 2010 to September 1, 2016, and included the following terms related to osteoporosis: fracture risk assessment (FRAX), trabecular bone score (TBS), screening, low-impact fracture, fragility fracture, calcium supplementation and cardiovascular risk, calcium supplementation and stroke risk, frequency of bone density screening, primary prevention, diet, exercise, bone mineral density assessment, screening laboratory profile, bisphosphonates, glucocorticoids and bone mineral density, steroids and bone mineral density, transplantation and bone mineral density, body habitus, body mass index, cigarette smoking, calcium intake, vitamin D intake, alcohol, estrogen, zoledronic acid, calcitonin, raloxifene, denosumab, ligand inhibitor, teriparatide, calcitriol, combination therapy and abaloparatide.

In addition to the literature searches, articles were obtained by work group members and ICSI staff. Those vetted by the work group were included in the guideline when appropriate.

Number of Source Documents

120 articles were carried over from the 2012 guideline. In addition, 28 studies were identified in the 2017 literature search, while 7 were found by Institute for Clinical Systems Improvement (ICSI) members and work group members through individual searches. Twenty sources supported formal recommendations.

See the "Study Selection Flowchart" companion document (see the Availability of Companion Documents" field) for the flow of studies through the selection process.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence and Strength of Recommendations

Category	Quality Definitions	Strong Recommendation	Weak Recommendation
High Quality Evidence	Further research is very unlikely to change confidence in the estimate of	The work group is confident that the desirable effects of adhering to this	The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will

Category	Quality Definitions	Strong Recommendation	Weak Recommendation
	effect.	recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients.	depend on local circumstances, patient values or preferences.
Moderate Quality Evidence	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.	The work group is confident that the benefits outweigh the risks, but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients.	The work group recognizes that there is a balance between harms and benefit, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances.
Low Quality Evidence	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change. The estimate or any estimate of effect is very uncertain.	The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.	The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The Institute for Clinical Systems Improvement (ICSI) utilizes the Grading of Recommendations Assessment (GRADE) methodology system. GRADE involves systematically evaluating the quality of evidence (high, moderate, low, very low) and developing a strength of recommendation (strong, weak).

In addition, when GRADE methodology could not be applied, the expert work group developed consensus recommendations.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Document Development and Revision Process

The development process is based on a number of long-proven approaches and is continually being revised based on changing community standards. The Institute for Clinical Systems Improvement (ICSI) staff, in consultation with the work group and a medical librarian, conduct a literature search to identify systematic reviews, randomized clinical trials, meta-analyses, other guidelines, regulatory statements and other pertinent literature. This literature is evaluated based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology by work group members. When needed, an outside methodologist is consulted.

The work group uses this information to develop or revise clinical flows and algorithms, write recommendations, and identify gaps in the literature. The work group gives consideration to the importance of many issues as they develop the guideline. These considerations include the systems of care in our community and how resources vary, the balance between benefits and harms of interventions, patient and community values, the autonomy of clinicians and patients and more. All decisions made by the work group are done using a consensus process.

ICSI's medical group members and sponsors review each guideline as part of the revision process. They provide comment on the scientific content, recommendations and implementation strategies. This feedback is used by and responded to by the work group as part of their revision work. Final review and approval of the guideline is done by ICSI's Committee on Evidence-Based Practice. This committee is made up of practicing clinicians and nurses, drawn from ICSI member medical groups.

Refer to the ICSI Scientific Document Development & Revision Process document (see the "Availability of Companion Documents" field) for additional information.

Rating Scheme for the Strength of the Recommendations

See the "Rating Scheme for the Strength of the Evidence" field.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Member Review

All Institute for Clinical Systems Improvement (ICSI) documents are available for member review at two points in the ICSI revision process. The ICSI Response Report is sent to members at the beginning of a document revision. The goal of this report is to solicit feedback about the guideline, including but not limited to the algorithm, content, recommendations and implementation. Members are also welcome to participate in the public comment period (see below).

Public Comment

ICSI makes a draft of the guideline available to the public on the ICSI Web site. The public is invited to comment in an effort to get feedback prior to its finalization. All comments will be reviewed by the ICSI facilitator and work group members when needed. ICSI work group may or may not make changes to the guideline based on public comment responses.

Refer to the original guideline document and to the ICSI Scientific Program document (see the "Availability of Companion Documents" field) for additional information.

Evidence Supporting the Recommendations

References Supporting the Recommendations

References Supporting the Recommendations

Black DM, Delmas PD, Eastell R, Reid IR, Boonen S, Cauley JA, Cosman F, Lakatos P, Leung PC, Man Z, Mautalen C, Mesenbrink P, Hu H, Caminis J, Tong K, Rosario-Jansen T, Krasnow J, Hue TF, Sellmeyer D, Eriksen EF, Cummings SR, HORIZON Pivotal Fracture Trial. Once-yearly zoledronic acid for treatment of postmenopausal osteoporosis. N Engl J Med. 2007 May 3;356(18):1809-22. PubMed

Black DM, Thompson DE, Bauer DC, Ensrud K, Musliner T, Hochberg MC, Nevitt MC, Suryawanshi S, Cummings SR, Fracture Intervention Trial. Fracture risk reduction with alendronate in women with osteoporosis: the Fracture Intervention Trial. J Clin Endocrinol Metab. 2000 Nov;85(11):4118-24. PubMed

Chen L, Wang G, Zheng F, Zhao H, Li H. Efficacy of bisphosphonates against osteoporosis in adult men: a meta-analysis of randomized controlled trials. Osteoporos Int. 2015 Sep;26(9):2355-63. PubMed

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Eisman JA, Civitelli R, Adami S, Czerwinski E, Recknor C, Prince R, Reginster JY, Zaidi M, Felsenberg D, Hughes C, Mairon N, Masanauskaite D, Reid DM, Delmas PD, Recker RR. Efficacy and tolerability of intravenous ibandronate injections in postmenopausal osteoporosis: 2-year results from the DIVA study. J Rheumatol. 2008 Mar;35(3):488-97. PubMed

Eriksen EF, DÃez-PÃ©rez A, Boonen S. Update on long-term treatment with bisphosphonates for postmenopausal osteoporosis: a systematic review. Bone. 2014 Jan;58:126-35. PubMed

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Hannan MT, Felson DT, Dawson-Hughes B, Tucker KL, Cupples LA, Wilson PW, Kiel DP. Risk factors for longitudinal bone loss in elderly men and women: the Framingham Osteoporosis Study. J Bone Miner Res. 2000 Apr;15(4):710-20. PubMed

Harris ST, Watts NB, Genant HK, McKeever CD, Hangartner T, Keller M, Chesnut CH 3d, Brown J, Eriksen EF, Hoseyni MS, Axelrod DW, Miller PD. Effects of risedronate treatment on vertebral and nonvertebral fractures in women with postmenopausal osteoporosis: a randomized controlled trial. Vertebral Efficacy With Risedronate Therapy (VERT) Study Group. JAMA. 1999 Oct 13;282(14):1344-52. PubMed

HÃ¸idrup S, GrÃ¸nbaek M, Gottschau A, Lauritzen JB, Schroll M. Alcohol intake, beverage preference, and risk of hip fracture in men and women. Am J Epidemiol. 1999 Jun 1;149(11):993-1001. PubMed

Huopio J, Kroger H, Honkanen R, Saarikoski S, Alhava E. Risk factors for perimenopausal fractures: a

prospective study. Osteoporos Int. 2000;11(3):219-27. PubMed

McClung MR, Geusens P, Miller PD, Zippel H, Bensen WG, Roux C, Adami S, Fogelman I, Diamond T, Eastell R, Meunier PJ, Reginster JY, Hip Intervention Program Study Group. Effect of risedronate on the risk of hip fracture in elderly women. Hip Intervention Program Study Group. N Engl J Med. 2001 Feb 1;344(5):333-40. PubMed

Miller PD, Recker RR, Reginster JY, Riis BJ, Czerwinski E, Masanauskaite D, Kenwright A, Lorenc R, Stakkestad JA, Lakatos P. Efficacy of monthly oral ibandronate is sustained over 5 years: the MOBILE long-term extension study. Osteoporos Int. 2012 Jun;23(6):1747-56. PubMed

Ulrich CM, Georgiou CC, Gillis DE, Snow CM. Lifetime physical activity is associated with bone mineral density in premenopausal women. J Womens Health. 1999 Apr;8(3):365-75. PubMed

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Shared decision-making (SDM) offers an opportunity to help the patient select a treatment to which they can adhere. When conversations discussing options occurs, patients and clinicians are actively engaged while considering the attributes and issues of the available options. This empathic approach results in the clinician and patient co-creating a decision and a plan of care.
- Physical activity, particularly weight-bearing exercise, is thought to provide the mechanical stimuli, or "loading," important for the maintenance and improvement of bone health. Resistance training may have more profound site-specific effect than aerobic exercise. High-intensity resistance training may have added benefits for decreasing fracture risks by improving strength and balance, and increasing muscle mass. High-impact exercise and weight training stimulate accrual of bone mineral content in the skeleton.
- Randomized clinical trials have shown exercise to decrease the risk of falls by approximately 25%. Stronger back extensor muscles have been shown to decrease the risk of vertebral fractures independent of pharmacotherapy. Those who exercise may fall differently and decrease their fracture risk as a result.
- Comprehensive reviews of the relationship of calcium intake and bone health reported that sufficient amounts of calcium slows age-related bone loss and may reduce osteoporotic fracture risk.
- Studies concerning vitamin D and bone health demonstrate daily vitamin D supplementation in the range of 700-800 international units can decrease hip fracture risk in the elderly by 26% and any non-vertebral fracture by 23%.
- Limiting alcohol use to no more than one drink per day for women and no more than two drinks per day for men will help to protect bone health and reduce the risk of falls.
- Anti-resorptive agents (bisphosphonates)
    - Alendronate (in both daily and weekly preparations) has been shown to increase BMD and reduce the incidence of vertebral, hip and non-vertebral fractures in postmenopausal women having existing vertebral fractures, and those with low BMD compared to placebo (calcium and vitamin D).
    - Risedronate, also available in daily and weekly preparations, has shown a 41% risk reduction in

the number of new vertebral fractures after three years compared to placebo in the VERT trial.
    - Daily and intermittent dosing of ibandronate has been shown to improve BMD and reduce vertebral fractures in 2,946 postmenopausal women with osteoporosis and vertebral fractures, compared with calcium and vitamin D alone.
    - Zoledronic acid improved BMD and decreased bone turnover markers for three years in the pivotal fracture trial.
- Adherence to therapy was associated with significantly fewer fractures at 24 months. Follow-up phone calls or visits have shown improvement in adherence.

See the "Benefit" and "Benefit-Harms Assessment" sections in the "Major Recommendations" field for additional benefits of specific interventions.

Potential Harms

- Spinal flexion exercises have demonstrated an increased risk of vertebral fractures.
- Taking calcium carbonate supplements on an empty stomach may increase the risk of kidney stones and may not be well absorbed. Over supplementation may be associated with an increased risk of kidney stones and vascular calcification.
- Bisphosphonates have the potential to cause abdominal pain, flatulence, indigestion, diarrhea, headache, fever, osteonecrosis of the jaw (ONJ), gastric ulcer, esophageal erosion, esophagitis, dysphagia, atypical fractures, rash, constipation, nausea, arthralgia, peripheral edema, myalgia, benign prostatic hyperplasia, hypertension, backache, pain in limb, bronchitis, upper respiratory infection, fatigue, asthenia, dizziness, atrial fibrillation, cardiac dysrhythmia, Stevens-Johnson syndrome, hypocalcemia, aseptic necrosis of bone of jaw.
- Adverse reaction to RANK ligand (RANKL) inhibitor include hypercholesterolemia, vomiting, anemia, arthralgia, backache, pain in limb, asthenia, cystitis, nasopharyngitis, upper respiratory infection, fatigue, endocarditis, cellulitis, dermatitis, hypocalcemia, anaphylaxis, hypersensitivity reaction, aseptic necrosis of bone of jaw, atypical fracture of femur and vertebral column, cancer.
- Recombinant parathyroid hormone (teriparatide) is shown to cause an increase in the incidence of osteosarcoma in male and female rats, dependent on dose and duration of treatment, hypotension, syncope, rash, sweating symptoms, hyperuricemia, constipation, diarrhea, indigestion, nausea, vomiting, arthralgia, spasm, asthenia, dizziness, rhinitis, increasing frequency of cough, pharyngitis, angina pectoris.
- Raloxifene (Evista) carries the risk of deep vein thrombosis and pulmonary embolism, hot sweats, leg cramp, and cerebrovascular accident.
- Conjugated estrogens/bazedoxifene acetate (Duavee) carries a risk of endometrial cancer, cardiovascular disorders and probable dementia. Other side effects include diarrhea, indigestion, nausea, upper abdominal pain, neck pain, spasm, dizziness, pain in throat, venous thromboembolism (VTE), cerebrovascular accident, retinal vascular disorder, primary malignant neoplasm of endometrium.
- Peripheral DXA (pDXA) is associated with exposure to trivial amounts of radiation.

See Appendix B in the original guideline document for a more complete list of adverse drug reactions. See also the "Harm" and "Benefit-Harm Assessment" sections in the Major Recommendations field for additional harms of specific interventions.

Contraindications

Contraindications

- Contraindications to alendronate include abnormalities of the esophagus that delay esophageal emptying, inability to stand or sit upright for at least 30 minutes, hypersensitivity to alendronate or any of its excipients, and hypocalcemia prior to beginning therapy. It is not recommended for

patients with creatinine clearance (CrCl) ≤35 mL/min.
- Contraindications to risedronate and risedronate delayed release include abnormalities of the esophagus that delay esophageal emptying, inability to stand or sit upright for at least 30 minutes, hypersensitivity to risedronate or any of its excipients, and hypocalcemia prior to beginning therapy. It is not recommended for patients with CrCl ≤30 mL/min.
- Contraindications to ibandronate include abnormalities of the esophagus that delay esophageal emptying, inability to stand or sit upright for at least 60 minutes, hypersensitivity to ibandronate or any of its excipients, and hypocalcemia prior to beginning therapy. It is not recommended for patients with CrCl ≤30 mL/min.
- Contraindications to zoledronic acid include hypersensitivity to zoledronic acid or any of its excipients and hypocalcemia prior to beginning therapy. It is not recommended for patients with CrCl ≤35 mL/min.
- Contraindications to denosumab include hypersensitivity to any component of the product, hypocalcemia prior to beginning therapy, and pregnancy.
- Contraindications to teriparatide include Paget's disease, any prior therapeutic radiation involving the skeleton, bone metastases or history of skeletal malignancies, metabolic bone disease (other than osteoporosis), hypercalcemia, pregnant and nursing women, unexplained elevated alkaline phosphatase, hypersensitivity, pediatric populations, or young adults with open epiphyses.
- Contraindications to raloxifene include pregnancy, history of venous thromboembolism, women who are pregnant or may become pregnant, and nursing women. For both anabolic agents, teriparatide and abaloparatide, use is approved for only two years. Cumulative use of abaloparatide and parathyroid hormone analogs (e.g., teriparatide) for more than two years during a patient's lifetime is not recommended.
- Contraindications to estrogens include history of venous thromboembolism, estrogen-dependent neoplasia, pregnancy, nursing women, uterine bleeding, and active or history of breast cancer, stroke, or myocardial infection. Its use is not recommended in women older than 75 years.

Qualifying Statements

Qualifying Statements

- The information contained in this Institute for Clinical Systems Improvement (ICSI) health care guideline is intended primarily for health professionals and other expert audiences.
- This ICSI health care guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI health care guideline and applying it in their individual case.
- This ICSI health care guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.
- There are very limited data from randomized controlled trials of alternative and complementary agents for prevention or treatment of osteoporosis.

Implementation of the Guideline

Description of Implementation Strategy

Implementation Tools and Resources

Criteria for Selecting Resources

For tools and resources specific to the topic of the guideline and selected by the work group, refer to the Implementation Tools and Resources Table in the original guideline document. Each item was reviewed thoroughly by at least one work group member. It is expected that users of these tools will establish the proper copyright prior to their use. The types of criteria the work group used are:

The content supports the clinical and the implementation recommendations.
Where possible, the content is supported by evidence-based research.
The author, source and revision dates for the content are included where possible.
The content is clear about potential biases and conflicts of interests and/or disclaimers are noted where appropriate.

Implementation Recommendations and Measures

These are provided to assist medical groups and others to implement the recommendations in the guidelines. Where possible, implementation strategies are included that have been formally evaluated and tested. Measures are included that may be used for quality improvement as well as for outcome reporting. When available, regulatory or publicly reported measures are included. Measure specifications are provided in the original guideline document.

Implementation Tools

Audit Criteria/Indicators

Chart Documentation/Checklists/Forms

Clinical Algorithm

Quick Reference Guides/Physician Guides

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Allen S, Forney-Gorman A, Homan M, Kearns A, Kramlinger A, Sauer M. Diagnosis and treatment of osteoporosis. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2017 Jul. 61 p.

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Jul

Guideline Developer(s)

Institute for Clinical Systems Improvement - Nonprofit Organization

Guideline Developer Comment

The Institute for Clinical Systems Improvement (ICSI) is comprised of 50+ medical group and hospital members representing 9,000 physicians in Minnesota and surrounding areas, and is sponsored by five nonprofit health plans. For a list of sponsors and participating organizations, see the ICSI Web site .

Source(s) of Funding

- The Institute for Clinical Systems Improvement (ICSI) provided the funding for this guideline revision. ICSI is a not-for-profit, quality improvement organization based in Bloomington, Minnesota. ICSI's work is funded by the annual dues of the member medical groups and three sponsoring health plans in Minnesota. Individuals on the work group are not paid by ICSI but are supported by their medical group for this work.
- ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups and sponsoring health plans review and provide feedback but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

Guideline Committee

Osteoporosis Work Group

Composition of Group That Authored the Guideline

Work Group Members: Ann Kearns, MD, PhD (*Work Group Leader*) (Mayo Clinic) (Endocrinology); Mary Homan, MD (Fairview Health Services) (Family Medicine); Alison Forney-Gorman, MD, MPH (HealthPartners Medical Group and Regions Hospital) (Family Medicine); Anne Kramlinger, MD (Mayo Clinic) (Family Medicine); Mary Sauer, PharmD, BCACP (North Memorial Health Care) (Family Medicine); Sharon Allen, MD, PhD (University of Minnesota Physicians) (Family Medicine); Jodie Dvorkin, MD, MPH (ICSI) (Project Manager/Health Care Consultant)

Financial Disclosures/Conflicts of Interest

The Institute for Clinical Systems Improvement (ICSI) has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report Clinical Practice Guidelines We Can Trust (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

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Guideline-Related Activities: None
Research Grants: None
Financial/Non-financial Conflicts of Interest: None

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Florence R, Allen S, Benedict L, Compo R, Jensen A, Kalogeropoulou D, Kearns A, Larson S, Mallen E, O'Day K, Peltier A, Webb B. Diagnosis and treatment of osteoporosis. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2013 Jul. 87 p. [210 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available for purchase from the Institute for Clinical Systems Improvement (ICSI) Web site. Also available to ICSI members for free at the ICSI Web site and to Minnesota health care organizations free by request at the ICSI Web site.

Availability of Companion Documents

The following are available:

ICSI scientific document development & revision process. Bloomington (MN): Institute for Clinical Systems Improvement. 1 p. Available from the Institute for Clinical Systems Improvement (ICSI) Web site.
ICSI scientific document program. Bloomington (MN): Institute for Clinical Systems Improvement. 2 p. Available from the ICSI Web site.

The following are provided to those who access the guideline (see the "Guideline Availability" field):

Diagnosis and treatment of osteoporosis. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement; 2017 Jul. 1 p.
Diagnosis and treatment of osteoporosis. Evidence table. Bloomington (MN): Institute for Clinical Systems Improvement; 2017 Jul. 5 p.
Diagnosis and treatment of osteoporosis. Study selection flowchart. Bloomington (MN): Institute for Clinical Systems Improvement; 2017 Jul. 1 p.

Additionally, the following are available in the appendices of the original guideline document:

Aims and measures (quality measures)
Secondary causes of osteoporosis
Medication summary table
ICSI shared decision-making model

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on December 24, 2002. The information was verified by the guideline developer on January 23, 2003. This summary was updated by ECRI on April 12, 2004, on September 16, 2004, on October 21, 2005, and September 18, 2006. This NGC summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs and most recently on January 2, 2009. This summary was updated by ECRI Institute on January 2, 2009. This summary was updated by ECRI Institute on July 20, 2009 following the U.S. Food and Drug Administration advisory on Varenicline and Bupropion. This summary was updated by ECRI Institute on December 10, 2010 following the U.S. Food and Drug Administration (FDA) advisory on Bisphosphonates. This summary was updated by ECRI Institute on July 15, 2011 following the U.S. Food and Drug Administration advisory on Chantix (varenicline). This NGC summary was updated by ECRI Institute on December 9, 2011. This summary was updated by ECRI Institute on January 14, 2013 following the revised U.S. Food and Drug Administration advisory on Chantix (varenicline). This summary was updated by ECRI Institute on February 10, 2014. This summary was updated by ECRI Institute on April 3, 2015 following the U.S. Food and Drug Administration advisory on Testosterone Products. This summary was updated by ECRI Institute on April 8, 2015 following the U.S. Food and Drug Administration advisory on Chantix (varenicline). This summary was updated by ECRI Institute on November 17, 2016 following the U.S. Food and Drug Administration advisory on Testosterone and Other Anabolic Androgenic Steroids (AAS). This summary was updated by ECRI Institute on January 31, 2018. The updated information was verified by the guideline developer on February 27, 2018.

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